28 January 2021
EMA/CHMP/622868/2020
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (initial authorisation)

Byfavo

remimazolam

On 28 January 2021, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of a marketing authorisation for the medicinal product Byfavo, intended for procedural sedation. The applicant for this medicinal product is PAION Netherlands B.V.

Byfavo will be available as a powder for solution for injection (20 mg). The active substance of Byfavo is remimazolam, an ultra-short acting benzodiazepine sedative (ATC code: N05CD14).

The benefits with Byfavo are its ability to induce sedation during diagnostic or therapeutic procedures. The most common side effects are hypotension, hypoxia and bradycardia.

The full indication is: "Remimazolam is indicated in adults for procedural sedation."

Byfavo should be administered by healthcare professionals experienced in sedation.

Detailed recommendations for the use of this product will be described in the summary of product characteristics (SmPC), which will be published in the European public assessment report (EPAR) and made available in all official European Union languages after the marketing authorisation has been granted by the European Commission.

[1] Summaries of positive opinion are published without prejudice to the Commission decision, which will normally be issued 67 days from adoption of the opinion

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